UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,384	07/26/2000	Richard A. Mueller	C-3128/1	8631

7590 01/14/2003

Pharmacia Corporation
Corporate Patent Department
P O Box 5110
Chicago, IL 60680

EXAMINER
ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/625,384	Applicant(s) MUELLER ET AL.	
	Examiner Binta M. Robinson	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-99 is/are pending in the application.

4a) Of the above claim(s) 1-18 and 38-99 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 19-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

Detailed Action

The applicant traverses the restriction requirement asserting that genus created by the examiner for examination purposes makes no sense, alleging that the group does not exist, because 't', 'R20', and 'R21' do not appear in Formula I. The applicant then goes on to assert that 't', 'R20' and 'R21' do exist in Formula II, but that t cannot be 2 in Formula II, thus the natural genus created by the examiner is allegedly erroneous. However, the examiner notes that the natural genus created around the elected species at paper no. 9 was not based on formula I. The examiner staed at paper no. 9 that Genus I was drawn to a compound of formula II in claim 19. where t can be 0 to 1, not 2.

The applicant then goes on to allege that the elected species, example 22 does not fit into the natural genus. However, the examiner notes that the elected species does fit into the natural genus of group I because R3 of formula II can equal alkyl, t can equal ~~1~~ 0, R1 can equal alkyl, R20 and R21 can equal alkyl, Y1 can equal Oxygen, R6 can equal H, R2 can equal alkylthioaryl, and R4 and R5 can form a nitrogen heterocyclic ring. All of these moieties define the moieties contained in example 22.

In the instant case the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under 35 USC 102(b) would not render obvious the same claim(s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense. Because these inventions are distinct for the

reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. This restriction is made **FINAL.**

The 112, first paragraph utility rejection of claim 33 is withdrawn in light of applicant's remarks at paper no. 8/B.

(old rejections)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33 in part is rejected under 35 U. S. C. 112, first paragraph for reasons of record at paper no. 7. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility, one skilled in the art clearly would not know how to use the claimed invention. Inhibiting a retroviral protease is a mechanism. The disease being treated by this inhibition is not stated. The specification must contain one practical utility in currently available form. The inhibition of an enzyme must be related to a disease that needs to be improved and this disease needs to be recited. There is no reasonable assurance that these will have all of the alleged properties since applicant does not show these compounds encompassing the wide Markush group are correlated to the treatment of specific diseases. The applicant is referred to In re Fouche 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is also referred to In re Wands, 858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte Foreman 230 USPQ 546 (Bd. Of App. And Inter. 1986).

Thus the fifth Wands factor of the predictability in the art of these compounds in treating certain diseases, the sixth Wands factor of the amount of direction provided by the inventor in terms of the use of these compounds for the treatment of specific diseases, and seventh Wands factor of the provision of working examples of the use of these compounds in the treatment of specific diseases are not satisfied. Additionally, the eighth Wands factor of the quantity of experimentation needed to make or use the invention based on the content of the disclosure is not satisfied. Undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claims are enabled by the instant specification.

2 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34 and 37 in part are rejected under 35 U. S. C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record at paper no. 7.

A. Claim 34 in part, the phrase "a retroviral infection" in line 1, page 184 is indefinite. The phrase is so broad. Which retroviral infection is the applicant claiming?

B. In claim 37, line 3, page 185, the phrase "in combination with other drugs" is indefinite. Which other drugs is the applicant claiming?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact

terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim s 19-37 in part are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the radicals R3 equaling all heterocyclic rings and R4 and R5 coming together with the nitrogen atom to which they are bonded to form all nitrogen heterocyclic rings. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to ***In re Wands***, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In

re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the breadth of the claims R3 and R4 and R5 encompass much wider markush groupings of radicals than those radicals tested which for R3 consists of methyl, and for R4 and R5 saturated isoquinoline. The nature of the invention of these compounds is that they are HIV protease inhibitors. In terms of the fifth Wands factor, the level of predictability in the art is low since only one compound falling within the elected restriction group were only tested for enzyme inhibition, antiviral activity, and cell toxicity, where the R3 is methyl, and the R4 and R5 come together to form saturated isoquinoline. The amount of direction provided by the inventor is poor, since the applicant only conducts tests for one compound falling within the elected group, where R3 is methyl, and the R4 and R5 come together to form saturated isoquinoline. The applicant does not test the whole breadth of compounds encompassing all of the moieties that these particular radicals can be. In terms of the seventh Wands factor, the applicant only provides one working example, that falls within the elected group of compounds.

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Response To applicant's Remarks

The 102 (b) nad 103 (a) rejection of claims 19-37 was withdrawn at paper

no. 9, so the applicant's response to this rejection is not necessary.

112, second paragraph rejection

Applicant's traverse the 112, second paragraph rejection of the phrase "a retroviral infection" in claim 34, alleging that retroviral infections are well known to the skilled practictioner and tha thte phrae is not indefinite. However, the applicant notes that retroviral infections encompass a broad array of infections and the applicant has not shown how all of these various retroviral infections or even most of them can be treated by the applicant's compounds.

Applicant's traverse the 112, second paragraph rejection of the phrase "in combination with other drugs" is not indefinite because the phrase "in combination with other drugs for the treatment of AIDS or the symptoms of AIDS", allegedly is not indefinite. However the phrase, "in combination with other drugs for the treatment of AIDS or the symptoms of AIDS" is indefinite because a vast array of drugs with varying structure exist that treat AIDS or the symptoms of AIDS.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson

January 5, 2003

Alan L. Rotman

ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600